

Onderzoek goedgekeurd door de RvB in de periode mei - augustus 2022 (St. Antonius Ziekenhuis)

Acroniem	Studietitel	Hoofdonderzoeker	Afdeling	Monocenter/ Multicenter	eigen geïnitieerd	WMO plichtig?
DUAL	Efficacy of Adductor Channel Block for anterior cruciate ligament surgery: A prospective double blinded randomized controlled trial	Timmerman, L.	Anesthesiologie	Multicenter	Ja	Ja
TRACE-NL	Evaluation of the safety, efficacy and cost-effectiveness of transcatheter tricuspid valve repair in patients with severe tricuspid regurgitation in the Netherlands	Timmers, L.	Cardiologie	Multicenter	Ja	Ja
ENABLE-CMR	Evaluation of ablation lesions using cardiovascular magnetic resonance imaging	Boersma, L.V.A.	Cardiologie	Monocenter	Ja	Ja
INIGMA studie	Indocyanine Green guided identification of sentinel lymph nodes via mastectomy incision in breast cancer patients (INIGMA study)	Doeksen, A.	Heelkunde	Monocenter	Ja	Ja
ACL shrinkage	Long-term outcome of ACL grafts shrinkage and an additional lemaire procedure in patients with residual instability after primary ACL reconstruction	Zijl, J.A.C.	Chirurgie/heelkunde	Multicenter	Ja	Nee
P-NOM	A comparison of in-hospital mortality of geriatric trauma patients with a hip fracture before versus after the implementation of the palliative non-operative management for frail geriatric patients.	Nijdam, T.M.P.	Chirurgie/heelkunde	Multicenter	Ja	Nee
Pain Type Hip Surgery	Postoperative pain in elderly patients after hip surgery: hemiarthoplasty compared to intramedullary osteosynthesis.	Nijdam, T.M.P.	Heelkunde	Multicenter	Ja	Nee
Post-bariatric abdominal pain management	Diagnosis and management of abdominal pain following gastric bypass surgery	Derksen, W.J.M.	Heelkunde	Multicenter	Ja	Nee
Translation and validation of the ICPW	Validation of the Infant Crying and Parent Well-Being (ICPW) screening tool in Dutch parents of infants less than 12 months of age	Vlieger, A.	Kindergeneeskunde	Multicenter	Ja	Nee
Prevalentie van onderliggende etiologie bij huilbaby's	Prevalence of underlying aetiologies in excessive crying infants	Kruijff de, I.	Kindergeneeskunde	Multicenter	Ja	Nee
Evaluation of psychotropic drug use in pregnancy and effect on the neonate	Evaluation of psychotropic drug use in pregnancy and effect on the neonate; a retrospective analysis	Vet, N.J.	Kindergeneeskunde	Multicenter	Ja	Nee
Verminderen delay screening anti-TNF-alfa remmers	Verminderen delay klinische patiënt met exacerbatie IBD	Sijbring, A.H.	MDL (maag-, darm- en leverziekten)	Multicenter	Ja	Nee
Preliminary results of factors associated with time to reach a stable axial length in atropine therapy in Dutch myopic children aged 6-15 years	Preliminary results of factors associated with time to reach a stable axial length in atropine therapy in Dutch myopic children aged 6-15 years	Beek- de Jong van der, L.K.	Oogheelkunde	Monocenter	Ja	Nee
De voorspellende waarde van cribriforme groei in de prostaatbipten voor gemetastaseerde ziekte op de PSMA.	The association between cribriform growth and positive lymph nodes and/or metastases on PSMA PET/CT	Heetman, J.	Urologie	Multicenter	Ja	Nee
Retrospectief onderzoek naar behandeling kleine niertumoren, cryoablatie en (partiele) nefrectomie	Resultaten van focale cryoablatie versus (partiele) nefrectomie in patiënten met kleine niertumoren (≤ 4 cm) in een hoog volume nierkanker centrum.	Melick van, H.H.E.	Urologie	Multicenter	Ja	Nee
Needs assessment for the development of a decision aid for patients with renal cell carcinoma	Designing a decision aid for patients with renal cell carcinoma: needs assessment	Melick van, H.H.E.	Value Based Healthcare	Multicenter	Ja	Nee

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LEGACY	Less Bleeding by Omitting Aspirin in Non-ST-segment Elevation Acute Coronary Syndrome Patients	Berg ten, J.M.	Cardiologie	Multicenter	Nee	Ja
CEPRA	The Cerebro Placental Ratio as indicator for delivery in perception of reduced fetal movements.	Heus de, R.	Gynaecologie	Multicenter	Nee	Ja
RIGHT	Implementation of optimized and standardized surgical technique for right-sided colon cancer: a prospective interventional sequential cohort study with a transition period	Smits, A.B.	Heelkunde	Multicenter	Nee	Ja
CLEAR-PATH	A randomized placebo-controlled double-blind trial studying the effect of antiplatelet monotherapy (clopidogrel) versus dual antiplatelet therapy (clopidogrel/acetysalicylic acid) on the occurrence of atherothrombotic events following lower extremity peripheral transluminal angioplasty	Bakker, O.J.	Heelkunde	Multicenter	Nee	Ja
PULSE	PLASOMA Ultimate Safety and Efficacy Study	Bakker, O.J.	Heelkunde	Multicenter	Nee	Ja
MajesTEC-7	A Phase 3 Randomized Study Comparing Teclistamab in Combination with Daratumumab SC and Lenalidomide (Tec-DR) versus Daratumumab SC, Lenalidomide, and Dexamethasone (DRd) in Participants with Newly Diagnosed Multiple Myeloma Who are Either Ineligible or not Intended for Autologous Stem Cell Transplant as Initial Therapy	Nijhof, I.S.	Interne geneeskunde	Multicenter	Nee	Ja
MK3475-587	A Multicenter, Open-label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants with Advanced Tumors Who Are Currently on Treatment or in Follow-up in a Pembrolizumab Trial	Los, M.	Interne geneeskunde	Multicenter	Nee	Ja
Mountaineer	An Open-label Randomized Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer	Los, M.	Interne geneeskunde	Multicenter	Nee	Ja
Enhance-3	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Magrolimab versus Placebo in Combination with Venetoclax and Azacitidine in Newly Diagnosed, Previously Untreated Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy	Weerdt de, O.	Interne geneeskunde	Multicenter	Nee	Ja
DIRECT-CD	"A Prospective Multicenter Randomized Controlled, Open-label Study to Compare the Efficacy of Subcutaneous Infliximab Monotherapy with Subcutaneous Infliximab and Concomitant Immunosuppression in the Treatment of Moderate to Severe Crohn's Disease." (DIRECT CD)	Mahmmod, N.	Interne geneeskunde	Multicenter	Nee	Ja
NIS793B12301	A randomized, double-blind, phase III study comparing NI5793 in combination with gemcitabine and nab-paclitaxel versus placebo combined with gemcitabine and nab-paclitaxel for first line treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC)	Los, M.	Interne geneeskunde	Multicenter	Nee	Ja
COSTAR Lung	A Randomized, pen-Label Phase 2/3 Study Comparing CObolimab + Dostarlimab +Docetaxel to Docetaxel Alone In Participants with Advanced Nonsmall Cell Lung Cancer Who Have Progressed on Prior Anti-PD-(L)1 Therapy and Chemotherapy	Kastelij, E.A.	Longziekten	Multicenter	Nee	Ja
NSCLC Platform	A Phase 2, Randomized, Open-label, Platform Study Utilizing a Master Protocol to Evaluate Novel Immunotherapy Combinations in Participants with Previously Untreated, Locally Advanced/Metastatic, Programmed Death Ligand 1-Selected Non-Small-Cell Lung Cancer	Kastelij, E.A.	Longziekten	Multicenter	Nee	Ja
ATYR1923-C-004	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Efzofitimod in patients with Pulmonary Sarcoidosis.	Veltkamp, M.	longziekten	Multicenter	Nee	Ja

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CADPT09A12201	A participant- and investigators-blinded, randomized, placebo-controlled, multicenter, platform study to investigate efficacy, safety, and tolerability of various singel treatments in participants with idiopathic pulmonary fibrosis	Veltkamp, M.	Longziekten	Multicenter	Nee	Ja
BI 1305-0023	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over 52 weeks in patients with Progressive Fibrosing Interstitial Lung Disease (PF-ILD)	Veltkamp, M.	Longziekten	Multicenter	Nee	Ja
BI 1305-0014.	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over 52 weeks in patients with IPF	Veltkamp, M.	Longziekten	Multicenter	Nee	Ja
IPF Comfort	A DOUBLE-BLIND, RANDOMISED, PLACEBO CONTROLLED, TWO PERIOD CROSS-OVER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ORVEPITANT IN CHRONIC COUGH IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS	Veltkamp, M.	Longziekten	Multicenter	Nee	Ja
VAD044	A randomised, placebo controlled, double blind, multicentre proof of concept study to assess the safety and efficacy of two doses of VAD044 in patients with hereditary haemorrhagic telangiectasia (HHT)	Mager, J.J.	Longziekten	Multicenter	Nee	Ja
INSPECCT	Cholangioscopy in intraductal staging of resectable extrahepatic CholangioCarcinoma	Verdonk, R.C.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Ja
MAD	Investigator led, double-masked, multicentre, randomized clinical trial for the comparison of atropine 0.5% versus atropine 0.05% eye drops for the prevention of myopia progression in Dutch children	Beek- de Jong van der, L.K.	Oogheelkunde	Multicenter	Nee	Ja
OPRAH	A multicentre, assessor-blinded, randomized controlled trial to investigate the effectiveness of a blended intervention, focused on personal feedback and coaching regarding physical activity and protein intake, after discharge in patients who have undergone elective gastro-intestinal or lung cancer surgery	Smits, A.B.	Revalidatie	Multicenter	Nee	Ja
SUNRISE	A Phase 3, Open-Label, Multi-Center, Randomized Study Evaluating the Efficacy and Safety of TAR-200 in Combination with Cetrelimab Versus Intravesical Bacillus Calmette-Guérin (BCG) in Participants with BCG-naïve High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)	Bergh van den, R.C.N.	Urologie	Multicenter	Nee	Ja
CAPACITY-COVID	Cardiac complicAtions in Patients with SARS Corona virus 2 regisTrY (CAPACITY-COVID)".	Berg ten, J.M.	Cardiologie	Multicenter	Nee	Nee
SECRET	Spatial location of breast cancer local rECurRence aftEr masTectomy: The SECRET study a retrospective analysis	Doeksen, A.	Heelkunde	Multicenter	Nee	Nee
PUCCINI	Percutaneous Closure Device Controlled Incraft Stentgraft Implantation Registry	Lammeren van, G.W.	Heelkunde	Multicenter	Nee	Nee
Breast cancer mimicking infectious breast diseases	Breast cancer mimicking infectious breast diseases: aetological, microbiological and pathological aspects'	Doeksen, A.	Heelkunde	Multicenter	Nee	Nee
The QUILT study: a stepped wedge cluster randomized trial study	'The Quilt study: quilting sutures in patients undergoing breast cancer surgery: a stepped wedge cluster randomized trial study' SDB 2022-005	Doeksen, A.	Heelkunde	Multicenter	Nee	Nee
TURN-COVID	TURN-COVID: Nederlandse cohort studie ter evaluatie van het gebruik van neutraliserende monoklonale antilichamen en andere antivirale middelen tegen SARS-CoV-2.	Moeniralam, H.	Interne geneeskunde	Multicenter	Nee	Nee
Dialogica	DIALOGICA: DIALysis or not: Outcomes in older kidney patients with GeriatrIC Assessment SDB-2022-001	Bos, W.J.W.	Interne geneeskunde	Multicenter	Nee	Nee
Patiëntparticipatie bij de selectie van uitkomstindicatoren	Patiëntparticipatie bij de selectie van uitkomstindicatoren: gebeurt het in de praktijk en wat is de impact op het gebruik van de uitkomstinformatie", met SDB nummer 2022-004	Bos, W.J.W.	Interne geneeskunde	Multicenter	Nee	Nee
ALERT-CD	Real life management of Crohn's perianal fistula	Boeckel van, P.	MDL (maag-, darm- en leverziekten)	Multicenter	Nee	Nee

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Influenza-MI studie	Association between laboratory-confirmed influenza infection and myocardial infarction	Schaftenaar, E.	Medische microbiologie	Multicenter	Nee	Nee
PONTAC 3	Psychisch ontregeld in de Acute Zorg (PONTAC; Mentally Disregulated in Emergency Care) deel 3: interviews zorgprofessionals	Sanders, M.	SEH (Spoedeisende Eerste Hulp)	Multicenter	Nee	Nee
PONTAC-2	Psychisch ontregeld in de Acute Zorg (PONTAC-2; Mentally Disregulated in Emergency Care) deel 2: interviews patiënten	Sanders, M.	SEH (Spoedeisende Eerste Hulp)	Multicenter	Nee	Nee